IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 03-086-A)

In application of)	
Groneberg et al.)	Examiner: M. Seaman
Serial No. 10/823,377)	
Patent No. 7,425,631)	
Filed: April 12, 2004)	Group Art Unit: 1625
Issue Date: September 16, 2008)	
For: Compounds and Methods of Use)	

Mail Stop **Patent Ext.** Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. 1.705 (b)-(d)

Sir:

Responsive to the Determination of Patent Term Adjustment posted on the Patent Application Information Retrieval System (PAIR) as of the September 16, 2008 issue date of U.S. Patent No. 7,425,631, and in light of the recent ruling in *Wyeth v. Dudas*, No. 07-1492, slip op. (D.D.C. Sept. 30, 2008) the Patentees submit this Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(b)-(d). As stated in 37 C.F.R. 1.705(d):

If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

The '631 patent issued on September 16, 2008. This request is being submitted within two months of the issue date of the '631 patent, and complies with the deadline specified in 37 C.F.R. 1.705(d). In addition, given the recent ruling in *Wyeth*, which was decided on September 30, 2008 (after payment of the issue fee for the '631 patent), Patentees could not have raised this issue prior to payment of the issue fee. Thus, Patentees contend this request is timely.

The data available on PAIR indicates that the '631 patent has been granted a 442 day Patent Term Adjustment. Patentees submit that, due to the recent *Wyeth* decision, the correct Patent Term Adjustment should be 965 days. Patentees, therefore, request that the '631 patent be granted an additional 523 days of patent term.

Patentees agree with the Patent Office's initial determination, which, for purposes of this request and in keeping with the explanation provided in *Wyeth*, Patentees will refer to as the "A delay." In the "A delay" the Patent Office delayed prosecution by issuing the first communication 14 months plus $\underline{600}$ days after the filing of the application (37 CFR 1.703(a)(1)). In the "A delay" the Patentees delayed prosecution by filing a response to a Notice of Missing Parts 2 months plus 121 days after the mailing of the respective action (37 CFR 1.704(b)), filing a response to an Office Action 3 months plus $\underline{35}$ days after the mailing of the respective action (37 CFR 1.704(b)) and filing a paper in response to Notice of Allowance $\underline{2}$ days after the mailing of the notice of allowance (37 CFR 1.704(c)(9)). Therefore the Patentees were responsible for a total of $\underline{158}$ days delay. These delays result in an "A delay" of $\underline{442}$ days (600 – 158 = 442).

The Patent Office however has **not** included in the Patent Term Adjustment the days related to the "B delay," which are the days delay resulting from an application pending longer than three years. According to 37 C.F.R. 1.703(b):

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued...

The instant application was filed on April 12, 2004 and issued on September 16, 2008, which is 3 years plus <u>523</u> days after the filing date, resulting in a "B delay" of <u>523</u> days.

The *Wyeth* decision states that "the 'A period' and 'B period' overlap only if they occur on the same calendar day or days" (*Wyeth*, No. 07-1492, slip op. at 8). Thus, according to the *Wyeth* decision, Patentees are entitled to both the "A delay" of 442 days and the "B delay" of 523 days minus any overlap which occurs on the same calendar days. There is no overlap of the same calendar days between the "A delay" (442 days) and the "B delay" (523). Thus, the total Patent Term Adjustment due to both the "A" and "B" delays and minus the overlap is 965 days (442 + 523 = 965).

For these reasons, the Patent Term Adjustment for this case should be <u>965</u> days.

In light of the foregoing, the Patentees respectfully request that an additional 523 days of Patent Term Adjustment be added to the patent term for Patent Office delay, resulting in a total Patent Term Adjustment of 965 days. If a telephone conference would expedite the prosecution of this Request for Reconsideration of Patent Term Adjustment, please contact the undersigned agent as indicated below.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: October 17, 2008 By: /Kevin E. Noonan/

Kevin E. Noonan, Ph.D. Registration No. 35,303